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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,421	11/18/2005	Breda M Cullen	JJM5002USPCT	4759

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EXAMINER	
LEWIS, KIM M	

ART UNIT	PAPER NUMBER
3772	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,421	CULLEN ET AL.	
	Examiner	Art Unit	
	Kim M. Lewis	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,6,10,11,13 and 16-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,6,10,11,13 and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/6/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed 7/6/09 has been received and made of record. As requested claims 1 and 13 have been amended.

2. Claims 1, 5, 6, 10, 11, 13 and 16-18 are pending in the instant application.

Information Disclosure Statement

3. The information disclosure statement filed 7/6/09 has been received and made of record. Note the acknowledged form PTO -1449 or substitute for enclosed herewith.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 5, 6, 10, 13, 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 2,314,842 ("Watt et al.") in view of Jaschinski.

As regards claims 1, 10 and 16-18, Watt et al. substantially disclose applicant's claimed invention. More specifically, Watt discloses materials such as freeze-dried sponges that can be used as a wound dressing comprising a protein such as collagen complexed with oxidized regenerated cellulose (ORC), wherein the weight ratio of protein collagen and ORC is from 1:99.99 to 99.99:1, which fails within the range of applicant's claimed range (see abstract, page 3, para. 2, and example 1).

Watt et al. fail to disclose that the complex comprises silver from about 0.1 wt. % to about 2 wt. %. Jaschinski, however, teaches that it is known to treat oxidized cellulose with a silver based antibacterial agent in an amount of ***0.1 wt. % to 25 wt. %*** (col. 24, lines 37-51) in order to confer antibacterial properties to medical products for the inherent purpose of preventing bacterial growth.

In view of Jaschinski, it would have been obvious to one having ordinary skill in the art at the time the invention was made to treat the wound dressing material of Watt et al. with a silver based antibacterial agent, in order to prevent bacterial growth.

With respect to the newly amended range of 0.1 wt. % to 0.3 wt. %, the examiner contends that the claimed range lies inside the disclosed range of 0.1 wt% to 25 wt. %. Applicants should note that it has been held that in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed.Cir. 1990).

Re. claim 5, Jaschinski does not disclose the amount of silver in the products is from about 1 to about 50% by weight. However, it has been held that the optimization of proportions in a prior art device is a design consideration. *In re Reese*, 290 F.2d 839, 129 USPQ 402 (CCPA 1961).

As to claim 6, the disclosed sponge of Jaschinski is inherently a sheet.

As regards claim 13, as can be read from claim 1 above, Watt et al. in view of Jaschinski discloses a wound dressing material comprising a complex of oxidized cellulose with silver wherein the material comprises from abut 0.1% wt% to about 2 wt. % of silver". Neither Watt et al. nor Jaschinski teach a method for treating various ulcers comprising the step of "applying the wound dressing material directly to the surface of the wound. Applicant should first note that it has been held that where the preambular language is part of the definition of the invention, it provides a limitation. Diversitech Corp. v. Century Steps Inc., 850 F. 2d 675, 7 USSPQ2d 1315 (Fed. Cir.

1988). Where, however, the preambular language states a purpose or intended use for the invention, it is not a limitation, but merely an indication of a possible use or the environment in which the invention operates. *Loctite Corp. v. Ultraseal Ltd.,* 781 F. 2d 861, 228 USPQ 90 (Fed. Cir. 1985). In the instant case, the preamble is not a limitation. Thus, while Watt et al. and Jaschinski do not disclose that the products are for treating an ulcer, a type of wound, one having ordinary skill in the art would have found it *prima facie* obvious to apply the wound dressing (bandage) to a wound, such as an ulcer, in order to prevent the growth of bacteria due to the antibacterial treatment of the dressing and to also protect and cover the wound.

1. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Watt et al. in view of Jaschinski as applied to claim 11 above, and in further in view of U.S. Patent No. 3,032,182 ("Bechtold").

As regards claim 11, Watt et al.i fails to teach the wound dressing (bandage) is sterile and packaged in a microorganism-impermeable container. However, Bechtold discloses sterile packaging for use with dressing and various other medical products in order to provide sterilized medical products in a container (package) that prevents the growth of mold or bacteria (col. 3, lines 35-50).

In view of Bechtold, it would have been obvious to one having ordinary skill in the art to provide the modified wound dressing (bandage) of Watt et al. in a package for sterilizing the dressing (bandage) and preventing the growth of bacteria and mold.

Response to Arguments

2. Applicant's arguments filed 10/14/08 have been fully considered but they are not persuasive. Applicant primarily argues that the prior art of Jaschinski does not teach or suggest oxidized regenerated cellulose with silver and that Watt et al. does not teach or suggest that the complex comprises silver from about 0.1 wt. % to about 2 wt. %.

The examiner wishes applicant to note that due to the amendment, the previous rejections have been withdrawn. However, the examiner wishes to point out the following with respect to the combined rejection of Watt et al. in view of Jaschinski. Watt et al. discloses all features of claim 1, except the silver as presently claimed. Jaschinski discloses at col. 24, lines 37-51, that it is known to treat oxidized cellulose with a silver based antibacterial agent in an amount of 0.1 wt. % to about 25 wt. %. Thus, applicants' claimed range lies inside the disclosed range of Jaschinski. Applicants should note that it has been held that in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed.Cir. 1990).

Thus, Jaschinski teaches that it is known to add silver to a wound dressing in order to confer antibacterial properties to medical products for the inherent purpose of preventing bacterial growth. Furthermore, it would have been *prima facie* obvious to add the silver to the wound dressing in an amount anywhere between 0.1 wt. to 25 wt. % in order to achieve the desired result. Applicant should further note that while Jaschinski discloses oxidized cellulose instead of oxidized regenerated cellulose, it still

would have been obvious to one having ordinary skill in art to add silver to the oxidized regenerated cellulose since it is a wound dressing material that would benefit from the addition of silver in order to fight bacterial growth at the wound cite or within the dressing.

With respect to independent claim 13, the same rationale applies.

Applicant additionally states that the specification on page 20, lines 14-21, demonstrates that within this claimed range of the complex, the device exhibited unexpected superior results. Applicant should note that Jaschinski discloses preferable concentrations in the range of 0.1 wt. % to 0.5 wt. % (col. 24, lines 45-47). Thus, the use sliver in an amount of low weight percent was known to Jaschinski.

Response to Arguments

8. Applicant's arguments filed 7/6/09 have been fully considered but they are not persuasive. Applicant primarily argues the following:

1). the examiner has failed to establish a pima facie obviousness rejection as there is no suggestion nor disclosure that a complex of silver with oxidized regenerated cellulose be formed as part of a wound dressing;

2). there is no suggestion in the cited documents that lowering the silver content to the range of 0.1 wt. % to 0.3 wt. % would achieve the proliferative an anti-inflammatory effects identified by the present inventors; and

3). claim 11 is traversed based upon the arguments of nonobviousness with respect to Watt in view of Jaschinski.

In response to Applicants' argument with respect to there being no suggestion nor disclosure that a complex of silver with oxidized regenerated cellulose be formed as part of a wound dressing, Applicants should first note that the Abstract of Watt discloses that such complexes described therein are "…used especially for wound dressings and the like". Further, on page 4, lines 30-32, Watt recites, " [t]he materials according to the invention may be used as haemostats, for tissue replacement, topical wound dressings...". Thus, there is clearly a teaching/suggestion of using oxidized regenerated cellulose in a wound dressing. As to the silver, the examiner relies on Jaschinski for the known teaching of treating oxidized cellulose with a silver based antibacterial agent in an amount of 0.1wt. % to 25 wt % in order to confer antibacterial properties to medical products so as to prevent bacterial growth. Applicant should note that the addition of silver to medical products is not novel, and since Jaschinksi discloses the addition of silver at concentrations as low as 0.1 wt. %, Applicants invention is rendered obvious.

In response to Applicant's argument that there is no suggestion in the cited documents that lowering the silver content to the range of 0.1 wt. % to 0.3 wt. % would achieve the proliferative an anti-inflammatory effects identified by the present inventors, Applicants should note that the claims of the present invention do recite such language

as proliferative effects or anti-inflammatory effects, therefore, whether or not the combination of Watt in view of Jascinski discloses such effects is irrelevant.

Finally, in response to Applicants' argument with respect to claim 11, note the response to the arguments presented above with respect to Watts in view of Jascinski.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-4796. The examiner can normally be reached on Monday to Wednesday, from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kim M. Lewis/
Primary Examiner
Art Unit 3772

Kml
November 19, 2009